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10/591,203	06/22/2007	Robert J. Maier	235.0155 0101	7327
26813 7590 07/21/2010 MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581336 MINNEAPOLIS, MN 55458-1336				
EXAMINER				
DEVI, SARVAMANGALA J N				
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1645				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,203

Applicant(s)

MAIER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-8,10-17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1,3,5-8,10 and 22 is/are rejected.
- 7) ☒ Claim(s) 19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/06/10 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 05/06/10 in response to the non-final Office Action mailed 01/06/10.

Status of Claims

- 2) Claims 2, 4 and 18 have been cancelled via the amendment filed 05/06/10.
New claims 22-24 have been added via the amendment filed 05/06/10.
Claims 1, 3, 5-7, 11, 12, 13 and 19-21 have been amended via the amendment filed 05/06/10.

Claims 1, 3, 5-8, 10-17 and 19-24 are pending.

Claim 23 is withdrawn from examination based upon election by original presentation.

Claims 1, 3, 5-8, 10, 19-22 and 24 are under prosecution.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objections to the specification made in paragraphs 7(A) and 7(B) of the Office Action mailed 01/06/10 is withdrawn in light of Applicants' amendment to the specification.
- 6) The objection to claim 1 made in paragraph 16 of the Office Action mailed 01/06/10 is withdrawn in light of Applicants' amendment to the claim.
- 7) The objection to claim 5 made in paragraph 16 of the Office Action mailed 01/06/10 is withdrawn in light of Applicants' amendment to the claim.
- 8) The objection to claim 6 made in paragraph 16 of the Office Action mailed 01/06/10 is

withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Moot

9) The rejection of claims 2 and 4 made in paragraph 10(a) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 18 made in paragraphs 10(e) and 10(i) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claims 2, 4 and 18 made in paragraph 12 of the Office Action mailed 01/06/10 under 35 U.S.C. § 102(b) as being anticipated by Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

12) The rejection of claim 21 made in paragraph 8 of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the deposit issue, is withdrawn upon Applicants' compliance with the deposit rules.

13) The rejection of claim 3 made in paragraph 10(a) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 7 made in paragraph 10(b) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claim 3 made in paragraph 10(c) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim or the base claim.

16) The rejection of claim 3 made in paragraph 10(d) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 19 made in paragraph 10(f) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 20 made in paragraph 10(g) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 21 made in paragraph 10(h) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claims 3, 5, 8, 10, 19 and 21 made in paragraph 10(i) of the Office Action mailed 01/06/10 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

21) The rejection of claims 1, 3 and 5-7 made in paragraph 12 of the Office Action mailed 01/06/10 under 35 U.S.C. § 102(b) as being anticipated by Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986), is withdrawn in light of Applicants' amendment to the claims and/or the base claim. A new rejection is set forth below to address the claims as amended.

22) The rejection of claim 8 made in paragraph 14 of the Office Action mailed 01/06/10 under 35 U.S.C. § 103(a) as being unpatentable over Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986) as applied to claim 7 above, is withdrawn in light of Applicants' amendment to the base claim.

23) The rejection of claim 10 made in paragraph 15 of the Office Action mailed 01/06/10 under 35 U.S.C. § 103(a) as being unpatentable over Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986) as applied to claim 7 above and further in view of Raettig Hansujurgen (US 3651214 A), is withdrawn in light of Applicants' amendment to the base claim.

Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

24) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

25) Claims 3 and 19-22 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) New claim 22 is indefinite and confusing in the limitation: 'bacterium of claim 1 wherein NiFe hydrogenase activity expressed by the cell'. Claim 1 does not recite 'expression' of NiFe hydrogenase activity by a cell. Claim 1 recites an isolated bacterium that does not express a functional NiFe hydrogenase protein.

(b) New claim 22 is further indefinite because it has improper antecedent basis in the limitation: 'the cell'. Claim 22 depends from claim 1, which does not recite any cell.

(c) New claim 22 is indefinite and confusing in the limitation: 'wherein NiFe hydrogenase activity **expressed** by the cell is undetectable' [Emphasis added]. Claim 22 depends from claim 1, wherein the bacterium 'does not express' a functional NiFe hydrogenase protein. Does it mean that the NiFe hydrogenase activity *expressed* by the cell as recited in claim 22 is unrelated to the functional NiFe hydrogenase protein recited in claim 1, but is of an additional NiFe hydrogenase *expressed* by the cell at a sub-detectable level wherein the NiFe hydrogenase is not required to be functional NiFe hydrogenase? Clarification is requested.

(d) Claim 3, as amended, is indefinite in the limitation: 'each mutation prevents the expression of a functional NiFe hydrogenase protein'. Does it mean that each mutation prevents the expression of the same 'a functional NiFe hydrogenase protein'? Note that the dependent claim 19, as presented previously, recited that the mutations prevent expression of --the corresponding gene products--.

(e) Analogous rejection and criticism apply to claim 20, as amended.

(f) Claim 19 and 21, which depend directly or indirectly from claim 3 or claim 20, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

26) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

27) Claims 1 and 5-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kim *et al.* (*Appl. Environ. Microbiol.* 62: 1759-1763, 1996) as evidenced by Schlecht *et al.* (*Naturwissenschaften* 80: 9-17, 1993, abstract).

Kim *et al.* taught a suspension (i.e., composition) of an isolated heat-killed and/or irradiated cell of *S. typhimurium* strain ATCC 14028 (i.e., JSG210) in a phosphate buffer, i.e., pharmaceutically acceptable carrier. The composition comprised additional cells of *S. typhimurium*. See left column on page 1760; first two full paragraphs under 'Results'; paragraph bridging pages 1759 and 1760; and 'Discussion. The *S. typhimurium* strain ATCC 14028 (JSG210) of the prior art is the same strain described at lines 13 and 14 of page 17 of the instant specification. Because the prior art strain is killed, it is expected not to express functional NiFe hydrogenase protein, and is expected to be antigenic since it intrinsically comprises at least heat-resistant polysaccharide or cell wall antigens. The cell wall components such as lipopolysaccharide, a variety of membrane proteins, murein, and lipoprotein present in the additional *S. typhimurium* cells comprised in the prior art suspension composition inherently serve as immunologic adjuvants in light of what is known in the art. For instance, Schlecht *et al.* taught that gram negative bacterial cell wall components such as lipopolysaccharide, a variety of membrane proteins, murein, and lipoprotein can act as natural immunoadjuvants. See title and abstract of Schlecht *et al.*

Claims 1 and 5-8 are anticipated by Kim *et al.* The reference of Schlecht *et al.* is **not** used as a secondary reference in combination with the reference of Kim *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Kim *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

28) Claims 1, 3, 5, 6 and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sawers *et al.* (*J. Bacteriol.* 168: 398-404, 1986, of record).

Sawers *et al.* taught of the art-known, characterized and presently available isolated *hyd* mutants of *S. typhimurium* possessing chromosomal lesions and defective in all three hydrogenase isoenzymes and *lacking* all known hydrogen-linked functional activities. See paragraph bridging the two columns on page 398.

Claims 1, 3, 5, 6 and 20 are anticipated by Sawers *et al.*

Rejection(s) under 35 U.S.C § 103

29) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

30) Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kim *et al.* (*Appl. Environ. Microbiol.* 62: 1759-1763, 1996) as applied to claims 7 and 1 above and further in view of Raettig Hansjurgen (US 3651214 A, of record).

The teachings of Kim *et al.* are explained above, which do not disclose that their composition is in the form of a lyophilized powder.

However, having an art-known bacterial composition produced in a lyophilized powder form for the purpose of storage was routine and conventional in the art at the time of the invention. For example, Raettig Hansjurgen taught the routine lyophilization of a composition comprising *S. typhimurium* cells in accordance with any conventional lyophilization process. See paragraph bridging columns 4 and 5.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to lyophilize Kim's killed *S. typhimurium* composition into a lyophilized powder using any conventional lyophilization process as taught by Raettig Hansjurgen to produce the instant invention. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of convenient storage.

Claim 10 is *prima facie* obvious over the prior art of record.

Remarks

31) Claims 1, 3, 5-8, 10, 20 and 22 stand rejected.

Claim 24 is allowable.

Claims 19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

32) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

33) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

34) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

35) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

July, 2010